

**Interim Guidelines for Examination of Patent Applications
for Patent Subject Matter Eligibility**

In the mid-1990's, the USPTO sought to clarify the legal requirements for statutory subject matter with regard to computer-related inventions. See Examination Guidelines for Computer Related Inventions, 61 Fed. Reg. 7478 (1996). Subsequent to the publication of those guidelines, the Court of Appeals for the Federal Circuit issued opinions in State Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F.3d 1368, 47 USPQ2d 1596 (Fed. Cir. 1998) and AT&T Corp. v. Excel Communications, Inc., 172 F.3d 1352, 50 USPQ2d 1447 (Fed. Cir. 1999). These decisions explained that, to be eligible for patent protection, the claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." State Street, 149 F.3d at 1373-74, 47 USPQ2d at 1601-02. Since this time, the USPTO has seen increasing numbers of applications outside the realm of computer-related inventions that raise subject matter eligibility issues. In order to assist examiners in identifying and resolving these issues, the USPTO is issuing these interim examination guidelines to assist USPTO personnel in the examination of patent applications to determine whether the subject matter as claimed is eligible for patent protection.

The principal objective of these guidelines is to assist examiners in determining, on a case-by-case basis, whether a claimed invention falls within a judicial exception to statutory subject matter (i.e., is nothing more than an abstract idea, law of nature, or natural phenomenon), or whether it is a practical application of a judicial exception

**IV. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES
WITH THE SUBJECT MATTER ELIGIBILITY REQUIREMENT OF
35 U.S.C. § 101**

A. Consider the Breadth of 35 U.S.C. § 101 Under Controlling Law

Section 101 of title 35, United States Code, provides:

Whoever invents or discovers any new and useful process, machine,
manufacture, or composition of matter, or any new and useful improvement
thereof, may obtain a patent therefor, subject to the conditions and requirements
of this title.

As the Supreme Court held, Congress chose the expansive language of
35 U.S.C. § 101 so as to include “anything under the sun that is made by man.”
Diamond v. Chakrabarty, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980).

In Chakrabarty, 447 U.S. at 308-309, 206 USPQ at 197, the court stated:

In choosing such expansive terms as “manufacture” and “composition of
matter,” modified by the comprehensive “any,” Congress plainly contemplated
that the patent laws would be given wide scope. The relevant legislative history
also supports a broad construction. The Patent Act of 1793, authored by
Thomas Jefferson, defined statutory subject matter as “any new and useful art,
machine, manufacture, or composition of matter, or any new or useful
improvement [thereof].” Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318. The Act
embodied Jefferson’s philosophy that “ingenuity should receive a liberal
encouragement.” V Writings of Thomas Jefferson, at 75-76. See Graham v.

John Deere Co., 383 U.S. 1, 7-10 (148 USPQ 459, 462-464) (1966).

Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word “art” with “process,” but otherwise left Jefferson’s language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to “include anything under the sun that is made by man.” S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). [Footnote omitted]

This perspective has been embraced by the Federal Circuit:

The plain and unambiguous meaning of section 101 is that any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may be patented if it meets the requirements for patentability set forth in Title 35, such as those found in sections 102, 103, and 112. The use of the expansive term “any” in section 101 represents Congress’s intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in section 101 and the other parts of Title 35.... Thus, it is improper to read into section 101 limitations as to the subject matter that may be patented where the legislative history does not indicate that Congress clearly intended such limitations.

Alappat, 33 F.3d at 1542, 31 USPQ2d at 1556.

35 U.S.C. § 101 defines four categories of inventions that Congress deemed to be the appropriate subject matter of a patent: processes, machines, manufactures and compositions of matter. The latter three categories define “things” or “products”

while the first category defines “actions” (i.e., inventions that consist of a series of steps or acts to be performed). See 35 U.S.C. 100(b) (“The term ‘process’ means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”).

Federal courts have held that 35 U.S.C. § 101 does have certain limits. First, the phrase “anything under the sun that is made by man” is limited by the text of 35 U.S.C. § 101, meaning that one may only patent something that is a machine, manufacture, composition of matter or a process. See, e.g., Alappat, 33 F.3d at 1542, 31 USPQ2d at 1556; In re Warmerdam, 33 F.3d 1354, 1358, 31 USPQ2d 1754, 1757 (Fed. Cir. 1994). Second, 35 U.S.C. § 101 requires that the subject matter sought to be patented be a “useful” invention. Accordingly, a complete definition of the scope of 35 U.S.C. § 101, reflecting Congressional intent, is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent.

The subject matter courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging. These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon is not patentable. See, e.g., Rubber-Tip Pencil Co. v. Howard, 87 U.S. (20 Wall.) 498, 507 (1874) (“idea of itself is not patentable, but a new device by which it may be made practically useful is”); Mackay Radio & Telegraph Co. v. Radio Corp. of America,

306 U.S. 86, 94, 40 USPQ 199, 202 (1939) (“While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”); Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759 (“steps of ‘locating’ a medial axis, and ‘creating’ a bubble hierarchy . . . describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic ‘abstract idea’”).

The courts have also held that a claim may not preempt ideas, laws of nature or natural phenomena. The concern over preemption was expressed as early as 1852. See Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1852) (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132, 76 USPQ 280, 282 (1948) (combination of six species of bacteria held to be nonstatutory subject matter). Accordingly, one may not patent every “substantial practical application” of an idea, law of nature or natural phenomena because such a patent “in practical effect be a patent on the [idea, law of nature or natural phenomena] itself.” Gottschalk v. Benson, 409 U.S. 63, 71-72, 175 USPQ 673, 676 (1972).

B. Determine Whether the Claimed Invention Falls Within An Enumerated Statutory Category

To properly determine whether a claimed invention complies with the statutory invention requirements of 35 U.S.C. § 101, USPTO personnel must first identify whether the claim falls within at least one of the four enumerated categories of

patentable subject matter recited in section 101 (process, machine, manufacture or composition of matter).

In many instances it is clear within which of the enumerated categories a claimed invention falls. Even if the characterization of the claimed invention is not clear, this is usually not an issue that will preclude making an accurate and correct assessment with respect to the section 101 analysis. The scope of 35 U.S.C. § 101 is the same regardless of the form or category of invention in which a particular claim is drafted. AT&T, 172 F.3d at 1357, 50 USPQ2d at 1451 . See also State Street, 149 F.3d at 1375, 47 USPQ2d at 1602 wherein the Federal Circuit explained

The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to -- process, machine, manufacture, or composition of matter -- [provided the subject matter falls into at least one category of statutory subject matter] but rather on the essential characteristics of the subject matter, in particular, its practical utility.

For example, a claimed invention may be a combination of devices that appear to be directed to a machine and one or more steps of the functions performed by the machine. Such instances of mixed attributes, although potentially confusing as to which category of patentable subject matter it belongs in, does not affect the analysis to be performed by the examiner. Note that an apparatus claim with process steps is not classified as a “hybrid” claim; instead, it is simply an apparatus claim including functional limitations. See, e.g., R.A.C.C. Indus. v. Stun-Tech, Inc., 178 F.3d 1309 (Fed. Cir. 1998) (unpublished).

The burden is on the USPTO to set forth a prima facie case of unpatentability. Therefore if the examiner determines that it is more likely than not that the claimed subject matter falls outside all of the statutory categories, the examiner must provide an explanation. For example, a claim reciting only a musical composition, literary work, compilation of data, or legal document (e.g., an insurance policy) per se does not appear to be a process, machine, manufacture, or composition of matter. If the examiner can establish a prima facie case that a claim does not fall into a statutory category, that does not preclude complete examination of the application for satisfaction of all other conditions of patentability. The examiner must further continue with the statutory subject matter analysis as set forth below. Also, the examiner must still examine the claims for compliance with 35 U.S.C. §§ 102, 103, and 112.

If the invention as set forth in the written description is statutory, but the claims define subject matter that is not, the deficiency can be corrected by an appropriate amendment of the claims. In such a case, USPTO personnel should reject the claims drawn to nonstatutory subject matter under 35 U.S.C. § 101, but identify the features of the invention that would render the claimed subject matter statutory if recited in the claim.

C. Determine Whether the Claimed Invention Falls Within § 101 Judicial Exceptions – Laws of Nature, Natural Phenomena and Abstract Ideas

Determining whether the claim falls within one of the four enumerated categories of patentable subject matter recited in 35 U.S.C. § 101 (process, machine, manufacture or composition of matter) does not end the analysis because claims

directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible and therefore are excluded from patent protection. Diehr, 450 U.S. at 185, 209 USPQ at 7; accord, e.g., Chakrabarty, 447 U.S. at 309, 206 USPQ at 197; Parker v. Flook, 437 U.S. 584, 589, 198 USPQ 193, 197 (1978); Benson, 409 U.S. at 67-68, 175 USPQ at 675; Funk, 333 U.S. at 130, 76 USPQ at 281. “A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.” Le Roy, 55 U.S. (14 How.) at 175. Instead, such “manifestations of laws of nature” are “part of the storehouse of knowledge,” “free to all men and reserved exclusively to none.” Funk, 333 U.S. at 130, 76 USPQ at 281.

Thus, “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter” under Section 101. Chakrabarty, 447 U.S. at 309, 206 USPQ at 197. “Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.” Ibid. Nor can one patent “a novel and useful mathematical formula,” Flook, 437 U.S. at 585, 198 USPQ at 195; electromagnetism or steam power, O’Reilly v. Morse, 56 U.S. (15 How.) 62, 113-114 (1853); or “[t]he qualities of * * * bacteria, * * * the heat of the sun, electricity, or the qualities of metals,” Funk, 333 U.S. at 130, 76 USPQ at 281; see Le Roy, 55 U.S. (14 How.) at 175.

While abstract ideas, natural phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, natural phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of section 101, the claim must be considered as a whole

to determine whether it is for a particular application of an abstract idea, natural phenomenon, or law of nature, rather than for the abstract idea, natural phenomenon, or law of nature itself.

1. Determine Whether the Claimed Invention Covers Either a § 101 Judicial Exception or a Practical Application of a § 101 Judicial Exception

An examiner must ascertain the scope of the claim to determine whether it covers either a § 101 judicial exception or a practical application of a § 101 judicial exception. The conclusion that a particular claim includes a § 101 judicial exception does not end the inquiry because “[i]t is now commonplace that an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis in original); accord Flook, 437 U.S. at 590, 198 USPQ at 197; Benson, 409 U.S. at 67, 175 USPQ at 675. Thus, “[w]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.” Diehr, 450 U.S. at 188, 209 USPQ at 8-9 (quoting Mackay, 306 U.S. at 94); see also Corning v. Burden, 56 U.S. (15 How.) 252, 268, 14 L.Ed. 683 (1854) (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”).

2. Determine Whether the Claimed Invention is a Practical Application of an Abstract Idea, Law of Nature, or Natural Phenomenon (§ 101 Judicial Exceptions)

For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomenon. Diehr, 450 U.S. at 187, 209 USPQ at 8 (“application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”); Benson, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it “has no substantial practical application”).

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

- The claimed invention “transforms” an article or physical object to a different state or thing.
- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

a. Practical Application by Physical Transformation

The examiner first shall review the claim and determine if it provides a transformation or reduction of an article to a different state or thing. If the examiner finds such a transformation or reduction, the examiner shall end the inquiry and find that the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a transformation or reduction, the examiner has not determined as a final matter that the claim is non-statutory. The examiner must proceed in further inquiry.

b. Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory.

In determining whether a claim provides a practical application that produces a useful, tangible, and concrete result, the examiner should consider and weigh the following factors:

(1) “USEFUL RESULT”

For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP §

2107 and Fisher, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). In addition, when the examiner has reason to believe that the claim is not for a practical application that produces a useful result, the claim should be rejected, thus requiring the applicant to distinguish the claim from the three § 101 judicial exceptions to patentable subject matter by specifically reciting in the claim the practical application. In such cases, statements in the specification describing a practical application may not be sufficient to satisfy the requirements for section 101 with respect to the claimed invention. Likewise, a claim that can be read so broadly as to include statutory and nonstatutory subject matter must be amended to limit the claim to a practical application. In other words, if the specification discloses a practical application of a § 101 judicial exception, but the claim is broader than the disclosure such that it does not require a practical application, then the claim must be rejected.

(2) “TANGIBLE RESULT”

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection.” Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also

Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is “abstract.”

(3) “CONCRETE RESULT”

Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which requires a particular skill, to determine whether that process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary artisan in that field. An appropriate rejection under 35 U.S.C. § 101 should be accompanied by a lack of enablement rejection under 35 U.S.C. § 112, paragraph 1, where the invention cannot operate as intended without undue experimentation. See infra.

3. Determine Whether the Claimed Invention Preempts an Abstract Idea, Law of Nature, or Natural Phenomenon (§ 101 Judicial Exceptions)

Even when a claim applies a mathematical formula, for example, as part of a seemingly patentable process, the examiner must ensure that it does not in reality “seek[] patent protection for that formula in the abstract.” Diehr, 450 U.S. at 191, 209 USPQ at 10. “Phenomena of nature, though just discovered, mental processes, abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” Benson, 409 U.S. at 67, 175 USPQ at 675. One may not patent a process that comprises every “substantial practical application” of an abstract idea, because such a patent “in practical effect would be a patent on the [abstract idea] itself.” Benson, 409 U.S. at 71-72, 175 USPQ at 676; cf. Diehr, 450 U.S. at 187, 209 USPQ at 8 (stressing that the patent applicants in that case did “not seek to pre-empt the use of [an] equation,” but instead sought only to “foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process”). “To hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection.” Diehr, 450 U.S. at 192, 209 USPQ at 10. Thus, a claim that recites a computer that solely calculates a mathematical formula (see Benson) or a computer disk that solely stores a mathematical formula is not directed to the type of subject matter eligible for patent protection. If an examiner determines that the claimed invention preempts a § 101 judicial exception, the examiner must identify the abstraction, law of nature, or natural phenomenon and explain why the claim covers every substantial practical application thereof.

D. Establish on the Record a Prima Facie Case

The examiner should review the totality of the evidence (e.g., the specification, claims, relevant prior art) before reaching a conclusion with regard to whether the claimed invention sets forth patent eligible subject matter. The examiner must weigh the determinations made above to reach a conclusion as to whether it is more likely than not that the claimed invention as a whole either falls outside of one of the enumerated statutory classes or within one of the exceptions to statutory subject matter. “The examiner bears the initial burden ... of presenting a prima facie case of unpatentability.” In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If the record as a whole suggests that it is more likely than not that the claimed invention would be considered a practical application of an abstract idea, natural phenomenon, or law of nature, the examiner should not reject the claim.

After the examiner identifies and explains in the record the basis for why a claim is for an abstract idea with no practical application, then the burden shifts to the applicant to either amend the claim or make a showing of why the claim is eligible for patent protection. See, e.g., In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); see generally MPEP § 2107 (Utility Guidelines).